IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

DEANNA K. RENYER and DAVID W. BLOIR, Plaintiffs, -vs- PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.), Defendants.	]]]]]]]]]]]]	Civil No. **JURY TRIAL DEMANDED**

COMPLAINT

Mark B. Hutton
Lead Counsel
KS Bar #10112
Elizabeth L. Dudley
KS Bar #21582
HUTTON & HUTTON LAW FIRM, L.L.C.
8100 East 22nd Street North, Bldg. 1200
P.O. Box 638
Wichita, Kansas 67201-0638
Telephone: (316) 688-1166
Facsimile: (316) 686-1077
Trial.Lawyers@huttonlaw.com

Attorneys for Plaintiffs

– and –

Martha K. Wivell, Esq.
MN Bar #128090
Attorney at Law
Box 339
Cook, MN 55723
Telephone: (218) 666-0250
MWivell@MSN.com

Attorneys for Plaintiffs and Local Counsel

Dated: _____, 2008

Table of Contents

COMPLAINT

Plaintiffs, for their Complaint against Defendants, allege as follows:

I. INTRODUCTION.

1. This is a civil action seeking damages for personal injuries. The Plaintiffs assert product liability claims against Defendants PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.), (hereinafter referred to as "the PFIZER ENTITIES") arising from the design, manufacture, and sale of drugs known as Bextra ("BEXTRA") and Celebrex ("CELEBREX"). It is alleged by the Plaintiffs that BEXTRA and CELEBREX were defective and unreasonably dangerous products that caused their damages.

2. It is anticipated that these actions will be subject to transfer and consolidation for pretrial proceedings pursuant to 28 U.S.C.A. §1407 in the United States District Court for the District of Minnesota. *See In Re: Bextra and Celebrex Product Liability Litigation,* MDL 1699 (J.P.M.D.L., *filed* Sept. 6, 2005) (transfer order, attached as Exhibit "A"). Plaintiffs join their individual and several claims against Defendants into this one lawsuit because their claims arise out of the same transaction, occurrence or series of transactions or occurrences and questions of law and fact common to all Plaintiffs will arise in this action. FED. R. CIV. P. 20(a). Joinder of these parties and claims for transfer and pretrial proceedings would work to "secure the just, speedy and inexpensive determination of [this] action." FED. R. CIV. P. 1. Therefore, Plaintiffs have joined their claims in this Complaint.

II. THE PARTIES.

A. The Individual Plaintiffs.

3. Plaintiff, **DEANNA K. RENYER**, is an adult individual residing in Kansas.

4. Plaintiff, **DAVID W. BLOIR**, is an adult individual residing in Kansas.

B. The Defendants PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).

5. Defendant **PFIZER, INC**. ("PFIZER"), is a foreign, for-profit corporation. PFIZER is incorporated in Delaware and has its principal place of business in New York, New York. At all times material, PFIZER was and is in good standing and actively doing business in the State of Minnesota. On July 16, 2002, PFIZER announced its proposed acquisition of PHARMACIA CORPORATION ("PHARMACIA"). On April 16, 2003, PFIZER completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib under the trade name BEXTRA in Minnesota and throughout the United States and the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

6. Defendant **G.D. SEARLE LLC (FKA G.D. SEARLE & CO.)** ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000, SEARLE was acquired by PHARMACIA and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter

ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Valdecoxib under the trade name BEXTRA in Minnesota and throughout the United States and the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

7. Defendant **PHARMACIA CORPORATION** is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is now a wholly-owned subsidiary of PFIZER. At all relevant times, PHARMACIA, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Valdecoxib under the trade name BEXTRA in Minnesota and throughout the United States and the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

8. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER under the brand name CELEBREX. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, in part so that PFIZER could take full control of CELEBREX.

9. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted and misrepresented the risks, dangers, defects and disadvantages of BEXTRA and CELEBREX, and advertised, promoted, marketed, sold and distributed BEXTRA and CELEBREX as safe prescription

medications when, in fact, Defendants had reason to know, and did know, that BEXTRA and CELEBREX were not safe for their intended purposes, for the patients for whom they were prescribed, and for whom they were sold and that BEXTRA and CELEBREX caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

10. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants or those Defendants' predecessors in interest.

III. JURISDICTION AND VENUE.

11. This Court has subject matter jurisdiction under 28 U.S.C.A. §1332 (diversity jurisdiction). Plaintiffs and the PFIZER ENTITIES are citizens of different states and the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00).

12. This Court has personal jurisdiction over PFIZER, INC. and PHARMACIA CORPORATION who, at all times material, were and are licensed and registered to do business in Minnesota. G.D. SEARLE & CO.'s foreign corporation status was revoked effective March 5, 2004, and it no longer maintains a registered agent for process of service in Minnesota. G.D. SEARLE, LLC maintains a registered agent for service of process in Delaware: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. PFIZER, INC. maintains a registered agent for the service of process in Minnesota: CT Corporation System, Inc., 405 2nd Avenue South, Minneapolis, MN 55401. PHARMACIA CORPORATION maintains a registered agent for the service of process in Minnesota: CT Corporation System, Inc., 405 2nd Avenue South, Minneapolis, MN 55401. Plaintiffs, by bringing this action, submit to this Court's personal jurisdiction.

13. As this is a case based upon diversity jurisdiction, this Court applies the forum state's choice-of-law rules. *Glover v. Merck & Co., Inc.*, 345 F.Supp.2d 994, 997 (D. Minn. 2004). Therefore, Minnesota choice-of-law principles apply here. *Id.*

14. As it relates to statutes of limitation, the traditional rule in Minnesota is that such statutes are procedural and governed by the law of the forum. *Id.* The Minnesota statute of limitations applicable to this claim is four (4) years. *See* Minn. Stat. Ann. §541.05(2); *Tuttle v. Lorillard Tobacco Co.*, 118 F.Supp.2d 954, 961-962 (D. Minn. 2000) (wrongful death limitations do not apply to products liability claims in Minnesota). Since all of Plaintiffs' injuries occurred within the above time frame, their causes of action are timely filed.

15. Venue is proper in this District pursuant to 28 U.S.C.A. §1391. The PFIZER ENTITIES marketed, advertised and distributed the dangerous products in this District, thereby receiving substantial financial benefit and profits from sales of the dangerous products in this District, and reside in this District under 28 U.S.C.A. §1391(c), such that venue is proper.

16. At all relevant times herein, the PFIZER ENTITIES were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their products, BEXTRA and CELEBREX. The PFIZER ENTITIES at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including Minnesota) the aforementioned prescription drugs. The PFIZER ENTITIES do substantial business in the State of Minnesota and within this District, advertises in this District, receives substantial compensation and profits from sales of BEXTRA and

CELEBREX in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct herein, each Defendant acted as the agent for each of the other Defendants or those Defendants' predecessors in interest.

IV. FACTS COMMON TO ALL PLAINTIFFS.

BEXTRA:

17. There are a group of medications or drugs known as "non-steroidal anti-inflammatory drugs" or "NSAIDs." These *medications* are designed to relieve pain, inflammation and swelling. Common NSAIDs include aspirin and ibuprofen. While aspirin and ibuprofen are effective NSAIDs, they do cause some people to experience gastrointestinal complications.

18. In the last ten to fifteen years, a new generation of NSAIDs known as "COX-2 inhibitors" has been introduced to provide relief from pain, inflammation and swelling without gastrointestinal complications. A COX-2 inhibitor minimizes the effects of the COX-2 enzyme, while not interfering with the COX-1 enzyme which helps to protect the stomach's lining, gastrointestinal tract and kidney functions.

19. In 1999, a drug known as "Celebrex," that was originally developed by G.D. SEARLE, was approved by the U.S. Food and Drug Administration ("FDA") as the first COX-2 inhibitor. Shortly thereafter, PHARMACIA acquired G.D. SEARLE through its merger with the Monsanto Company.

20. By the end of 2000, PHARMACIA had submitted "parecoxib sodium," another COX-2 inhibitor, for FDA approval for acute pain management. Parecoxib sodium is a "pro-drug" for "valdecoxib." A pro-drug is a drug which is rapidly converted

in the body to the active form, which, in the case of parecoxib sodium, is valdecoxib. During studies, parecoxib sodium was associated with a cluster of cardiovascular events and was rejected by the FDA in 2001.

21. Thereafter, PHARMACIA submitted another COX-2 inhibitor, named "BEXTRA," which was Valdecoxib, to the FDA for approval.

22. The testing data provided by PHARMACIA was inadequate to disclose the dangerous properties of BEXTRA. If PHARMACIA had conducted adequate testing prior to FDA approval, rather than the short-duration studies on small patient groups, PHARMACIA's data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of BEXTRA consumers. Adequate testing would have shown that BEXTRA possessed serious side effects for individuals such as the Plaintiffs. PFIZER and its predecessors should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

23. PFIZER and its predecessors intentionally withheld information, suppressed data and limited studies to conceal the hazardous nature of COX-2 inhibitors and BEXTRA to obtain FDA approval and market their product to the public. PFIZER and its predecessors knew, from their experience with parecoxib sodium, the pre-drug to Valdecoxib or BEXTRA, that substantial evidence of adverse cardiovascular events would complicate or bar FDA approval. Therefore, PFIZER and its predecessors

intentionally manipulated the testing and data to conceal these adverse events associated with Valdecoxib or BEXTRA.

24. The FDA approved BEXTRA to treat the joint pain of osteoarthritis and adult rheumatoid arthritis on November 16, 2001. Since its introduction to the market, BEXTRA has been prescribed for people suffering from osteoarthritis, adult rheumatoid arthritis and menstrual cramping.

25. PFIZER acquired PHARMACIA on April 16, 2003, and is the successor-in-interest to PHARMACIA and G.D. SEARLE.

26. The use of BEXTRA grew rapidly with sales exceeding $900 million in 2003.

27. Later in November 2004, the PFIZER ENTITIES added a new warning to the BEXTRA label cautioning doctors that BEXTRA was associated with increased risk of thromboembolic events such as attack, stroke, pulmonary embolism or deep vein thrombosis immediately following cardiac artery bypass graph ("CABG") surgery. The warning stated:

> Patients treated with BEXTRA for pain following coronary artery bypass graft surgery have a higher risk for cardiovascular/ thromboembolic events, deep surgical infections or sternal wound complications. BEXTRA is therefore contraindicated for the treatment of postoperative pain following CABG surgery.
>
> BEXTRA is contraindicated for the treatment of post-operative pain immediately following coronary artery bypass graft surgery and should not be used in this setting.

28. The PFIZER ENTITIES limited the warning to patients who underwent CABG surgery. There was no warning associated with the use of BEXTRA for the treatment of osteoarthritis, adult rheumatoid arthritis and menstrual cramping.

29. On April 7, 2005, the FDA finally insisted that PFIZER "voluntarily withdraw" BEXTRA from the U.S. market, stating:

> [T]he overall risk versus benefit profile of BEXTRA is unfavorable. This conclusion is based on the potential increased risk for serious cardiovascular (CV) adverse events, which appears to be a class effect of non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin), an increased risk of serious skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other NSAIDs, and the fact that BEXTRA has not been shown to offer any unique advantage over the other available NSAIDs.

FDA ALERT FOR HEALTHCARE PROFESSIONALS (April 7, 2005).

CELEBREX:

A. Facts Regarding CELEBREX: Science and Other COX-2 Inhibitors.

30. CELEBREX is among a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve®) and ibuprofen (trade name Advil®) are examples of well-known NSAIDs.

31. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain and fever.

32. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

33. Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and

pain, but at the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

34. The PFIZER ENTITIES and other pharmaceutical companies set out to remedy these gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium; these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDS that inhibit both COX-1 and COX-2.

35. In making this decision, however, PFIZER and their predecessors-in-interest either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation, clotting and vasoconstriction, while leaving thromboxane A2 (a potent COX-1 platelet aggregator and vasoconstrictor), unaffected. By selectively inhibiting COX-2 (prostaglandin I2) without similarly suppressing its COX-1 counterpart, CELEBREX and other coxibs expose their

users to a host of clot-related cardiovascular risks, including heart attack, stroke, unstable angina and serious thromboembolic events.

36. On June 29, 1998, SEARLE and PFIZER filed for FDA approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998, for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

37. In April 2000, SEARLE was acquired by PHARMACIA and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER's acquisition of PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

38. In late January 1999, following FDA approval, the PFIZER ENTITIES publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. The PFIZER ENTITIES' massive marketing campaign fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. The PFIZER ENTITIES, their representatives and agents

misrepresented the safety profile of CELEBREX to consumers, the medical community, healthcare providers and third party payors.

B. Facts Regarding CELEBREX's Safety and the PFIZER ENTITIES' Knowledge Thereof.

39. The potential for cardiovascular risk of selective COX-2 inhibitors was known to the PFIZER ENTITIES long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, the PFIZER ENTITIES were aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

40. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with the PFIZER ENTITIES' launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro and may predispose patients to myocardial infarction or thrombotic stroke. Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2,*" N Engl J Med 2001; 345:433-442.

41. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon the PFIZER ENTITIES' representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the

blood clotting process." *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

42. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, the PFIZER ENTITIES knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

43. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, the PFIZER ENTITIES failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

C. CELEBREX and COX-2 Studies Did Not Show CELEBREX to be Safe.

1. CELEBREX Long-Term Arthritis Safety Study (CLASS).

44. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.).

45. On September 13, 2000, the PFIZER ENTITIES released the results of the CLASS study in the *Journal of American Medicine.* Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

46. Although the PFIZER ENTITIES touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not tolerate traditional NSAIDs in their gastrointestinal system, the PFIZER ENTITIES intentionally, recklessly and/or negligently concealed, suppressed, omitted and misrepresented the results, risks and defects of the CLASS study. Among other things, the PFIZER ENTITIES failed to release the study's complete twelve month results – releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors and understated known cardiovascular risks.

47. Despite the PFIZER ENTITIES' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and

ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

48. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs. (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

49. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002; 324:1287-1288. Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had twelve months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, the PFIZER ENTITIES relied on and published only the first six months of data. JAMA 2000, 48:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBREX. These results clearly contradict the published CLASS conclusions.

50. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5; Sect A:11. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent [GI] safety advantage disappeared."

51. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all sixteen CLASS authors were either employees of PHARMACIA or paid consultants of the company. Okie, S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5; Sect A:11. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to believe. *Id.* Here again, when the complete data was considered, most of CELEBREX's advantages disappeared.

52. The PFIZER ENTITIES also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the

American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones—all for cardiovascular risks. Debabrata Mukherjee, *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001). The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or CELEBREX, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

53. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original NDA submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo-treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

54. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events were 1.4% in the CELEBREX group versus 1.0% in either NSAID group. Specifically, the

rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

55. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically significant, was also found in the 6229 patients not taking aspirin in the trial. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX and jeopardizing countless lives in the process.

56. The CLASS data proves that the PFIZER ENTITIES knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

2. **APC Trial.**

57. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of

CELEBREX in preventing the growth of pre-cancerous colon polyps. N.ENG. J. MED. 352; 11 at 1072. The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

58. On December 17, 2004, the NCI suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke." Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of Coxibs,*" JAMA 293:366. Analysis by an independent Data Safety Monitoring Board ("DSMB") showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

59. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

60. The FDA reported similar results, noting:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the

> composite endpoint of death from CV causes, myocardial infarction (MI) or stroke.

April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

61. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. The PFIZER ENTITIES knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, the PFIZER ENTITIES were aware of "dosage creep."

3. **Other CELEBREX Trials.**

62. Several other CELEBREX trials also gave the PFIZER ENTITIES insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

63. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." Id.

4. **COX-2 Studies: VIGOR and APPROVe.**

64. The PFIZER ENTITIES also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, the PFIZER ENTITIES had knowledge of two studies conducted by Merck related to its COX-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

a. **VIGOR.**

65. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

66. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

67. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental

mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including the PFIZER ENTITIES, were aware of these results.

b. **APPROVE.**

68. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)."[1] *Public Citizen*, January 24, 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx, the PFIZER ENTITIES never paused to reevaluate the CELEBREX data and studies.

69. The scientific data available during and after CELEBREX's approval process made clear to the PFIZER ENTITIES that their formulation of CELEBREX would cause a higher risk of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

70. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining the PFIZER ENTITIES' failure to have conducted the necessary

[1] Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

71. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

72. Based upon readily available scientific data, the PFIZER ENTITIES knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, the PFIZER ENTITIES' testing and studies were grossly inadequate.

73. Had the PFIZER ENTITIES done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the PFIZER ENTITIES' scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. The PFIZER ENTITIES should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

74. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the PFIZER ENTITIES intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

75. The PFIZER ENTITIES' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

76. At the time the PFIZER ENTITIES manufactured, advertised and distributed CELEBREX to consumers, the PFIZER ENTITIES intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke, serious thromboembolic events and/or myocardial infarctions because the PFIZER ENTITIES knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

D. Facts Regarding the PFIZER ENTITIES' Marketing and Sale of CELEBREX.

77. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the PFIZER ENTITIES' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiffs, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

78. The PFIZER ENTITIES' marketing was so fraudulent that the FDA issued three Warning Letters to the PFIZER ENTITIES in October 1999, April 2000, and

November 2000, all finding that the PFIZER ENTITIES were unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

79. In February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regiments and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

80. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001, that, "the study had lasted a year, not six months as . . . thought. Almost all of the ulcer complications that occurred during the second half of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage [as compared to traditional NSAIDs] disappeared."

81. On January 10, 2005, the FDA again issued the PFIZER ENTITIES a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 CELEBREX] variously: omit material facts … and make misleading safety, unsubstantiated superiority and unsubstantiated

effectiveness claims." Amid continued frustration with the PFIZER ENTITIES continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [CELEBREX].

82. At all times relevant herein, the PFIZER ENTITIES engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

83. The PFIZER ENTITIES widely and successfully marketed CELEBREX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis and related problems. The PFIZER ENTITIES made misrepresentations by means of media advertisements and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

84. Despite knowledge of the dangers presented by CELEBREX, PFIZER and its predecessors-in-interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiffs, of the serious risk of injury occasioned by the defects inherent in CELEBREX. The PFIZER ENTITIES and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. The PFIZER ENTITIES' conduct was

wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

85. In an elaborate and sophisticated manner, the PFIZER ENTITIES aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from the PFIZER ENTITIES' successful advertising and marketing blitz, third party payors were compelled to add CELEBREX to their formularies. The PFIZER ENTITIES' marketing campaign specifically targeted third party payors, physicians and consumers and was designed to convince them of both therapeutic and economic value of CELEBREX.

86. The PFIZER ENTITIES represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). The PFIZER ENTITIES promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

87. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, myocardial infarctions (heart attacks), deep vein thrombosis, pulmonary emboli, hypertension and cerebrovascular events, such as strokes. In addition, CELEBREX is significantly more expensive than traditional NSAIDs (costing $3.00 to

$6.00 per day for CELEBREX versus $0.50/day for over the counter NSAIDs). Moreover, CELEBREX was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers and gastrointestinal bleeding. Yet, the PFIZER ENTITIES chose not to warn about these risks and dangers.

88. The PFIZER ENTITIES knew of these risks before the FDA approved CELEBREX for sale, but the PFIZER ENTITIES ignored, downplayed, suppressed, omitted and concealed these serious safety risks and denied the lack of efficacy in its promotion, advertising, marketing and sale of CELEBREX. The PFIZER ENTITIES' omission, suppression and concealment of this important information enabled CELEBREX to be sold to, and purchased or paid for by, the Consumers at a grossly inflated price.

89. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded $2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

90. Because the PFIZER ENTITIES engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers that touted CELEBREX as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, the PFIZER ENTITIES were able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had the PFIZER ENTITIES disclosed the truth about CELEBREX, the PFIZER ENTITIES would not and could not have reaped the billions of

dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression and obfuscation of the truth.

91. The PFIZER ENTITIES intentionally, deliberately, knowingly and actively concealed, omitted, suppressed and obfuscated important and material information regarding the risks, dangers, defects and disadvantages of CELEBREX from Plaintiffs, the public, the medical community and the regulators. This concealment and omission was deliberate, knowing, active and uniform, was intended to induce and maximize sales and purchases of CELEBREX and prevented Plaintiffs from obtaining all the material information that would be important to their decision as a reasonable person to purchase, pay for and/or use CELEBREX.

92. The PFIZER ENTITIES' systematic, active, knowing, deliberate and uniform concealment, omissions, suppression and conduct caused Plaintiffs to purchase, pay for and/or use CELEBREX; and caused Plaintiffs' losses and damages as asserted herein.

93. Had the PFIZER ENTITIES done adequate testing prior to approval and "market launch," the PFIZER ENTITIES' scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. The PFIZER ENTITIES should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

94. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but the PFIZER ENTITIES intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

95. The PFIZER ENTITIES' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. The PFIZER ENTITIES were well aware that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

96. The PFIZER ENTITIES' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

97. At the time the PFIZER ENTITIES manufactured, advertised and distributed CELEBREX to consumers including Plaintiffs, the PFIZER ENTITIES intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, serious thromboembolic events, stroke and/or myocardial infarctions because the PFIZER ENTITIES knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

V. INDIVIDUAL PLAINTIFF'S STATEMENT OF FACTS.

A. PLAINTIFF DEANNA K. RENYER

98. Plaintiff DEANNA K. RENYER was prescribed CELEBREX on February 22, 2002. She took it daily and was still taking it on November 2, 2002, a period of seven and one-half months, at which time she was admitted to the hospital with a sudden onset of chest pain. Ms. Renyer was diagnosed with an acute myocardial infarction requiring angioplasty [heart attack]. CELEBREX caused or contributed to cause the stroke which she suffered on November 2, 2002, along with other injuries and damages.

99. Unaware of the risks presented by CELEBREX, or that CELEBREX was the cause of her injuries, Ms. Renyer continued to take CELEBREX until November 20, 2002. Ms. Renyer and her healthcare providers were, at the time of her injuries, unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of CELEBREX. Plaintiff and her healthcare providers never knew of the significant increased risks of heart attack caused by CELEBREX until various information was released sometime thereafter.

100. As a result of the PFIZER ENTITIES' wrongful acts, Ms. Renyer suffered severe and permanent personal injuries as described above due to her prescribed consumption of CELEBREX. As a result of the severe and permanent personal injuries as described above, Ms. Renyer incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Ms. Renyer has endured and will continue to endure pain, suffering, disability, mental anguish and disfigurement, causing additional damages. These damages exceed $75,000.00.

B. PLAINTIFF DAVID W. BLOIR

101. Plaintiff DAVID W. BLOIR was prescribed BEXTRA on October 4, 2002, which he took for one month and was still taking it on November 8, 2002, at which time he was admitted to the hospital complaining of chest pain. Mr. Bloir was diagnosed an acute myocardial infarction [heart attack]. BEXTRA caused or contributed to cause the heart attack which he suffered on November 8, 2002, along with other injuries and damages.

102. Unaware of the risks presented by BEXTRA, or that BEXTRA was the cause of his injuries, Mr. Bloir continued to take BEXTRA until November 30, 2004. Mr. Bloir and his healthcare providers were, at the time of his injuries, unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of BEXTRA. Plaintiff and his healthcare providers never knew of the significant increased risks of heart attack caused by BEXTRA until various information was released sometime thereafter.

103. As a result of PFIZER's wrongful acts, Mr. Bloir suffered severe and permanent personal injuries as described above due to his prescribed consumption of BEXTRA. As a result of the severe and permanent personal injuries as described above, Mr. Bloir incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Mr. Bloir has endured and will continue to endure pain, suffering, disability, mental anguish and disfigurement, causing additional damages. These damages exceed $75,000.00.

VI. CLAIMS FOR RELIEF.

A. Count I: Strict Liability.

104. Plaintiffs adopt by reference Paragraphs 1 through 103.

105. PFIZER and its predecessors-in-interest were engaged in the business of researching, designing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling and distributing drugs and pharmaceutical products, particularly including BEXTRA and CELEBREX as described above.

106. BEXTRA and CELEBREX were and are defective and unreasonably dangerous to persons, like Plaintiffs herein, who might be expected to use the products. BEXTRA and CELEBREX were in a defective condition because they were unsafe for normal or anticipated handling and consumption. BEXTRA and CELEBREX were unreasonably dangerous as the products were dangerous to an extent beyond that which would be contemplated by the ordinary consumer, like Plaintiffs herein, who purchased it and used it, with the ordinary knowledge common to the community as to its characteristics. BEXTRA and CELEBREX were also unreasonably dangerous because the drugs, due to their dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller assuming they knew of their dangerous condition. BEXTRA and CELEBREX were defective and unreasonably dangerous in design, manufacturing, instructions and warnings.

107. BEXTRA and CELEBREX were defective and unreasonably dangerous at the time the products left the PFIZER ENTITIES' control.

108. BEXTRA and CELEBREX were expected to reach and did reach Plaintiffs without substantial change in the condition in which the products were manufactured and sold.

109. The defects in BEXTRA and CELEBREX and the PFIZER ENTITIES' other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

110. WHEREFORE, Plaintiffs individually demand and pray for judgment against the PFIZER ENTITIES in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

B. Count II: Breach of Implied Warranty of Merchantability.

111. Plaintiffs adopt by reference Paragraphs 1 through 110.

112. PFIZER and its predecessors are merchants as to its drugs and pharmaceutical products, particularly including BEXTRA and CELEBREX described above. BEXTRA and CELEBREX and other drugs and pharmaceutical products are goods.

113. The PFIZER ENTITIES, as a merchant, impliedly warranted the merchantability of its drugs and pharmaceutical products, including BEXTRA and CELEBREX.

114. BEXTRA and CELEBREX were not merchantable as impliedly warranted. Specifically, but not exclusively, BEXTRA and CELEBREX were not fit for the ordinary purposes for which there were used because: (1) they caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including

heart attacks, strokes and other serious and harmful adverse health effects, and (2) were not effective in decreasing gastrointestinal side effects.

115. Plaintiffs, as consumers of BEXTRA and CELEBREX, were reasonably expected to use, consume and/or be affected by BEXTRA and CELEBREX.

116. The PFIZER ENTITIES' breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

117. WHEREFORE, Plaintiffs individually demand and pray for judgment against the PFIZER ENTITIES in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

C. Count III: Breach of Implied Warranty of Fitness for a Particular Purpose.

118. Plaintiffs adopt by reference Paragraphs 1 through 117.

119. PFIZER and its predecessors, as merchants and sellers of drugs and pharmaceutical products, including BEXTRA and CELEBREX as described above, knew or had reason to know of the particular purpose for which its goods were used.

120. The buyer of BEXTRA and CELEBREX relied upon the PFIZER ENTITIES' skill and judgment to select and furnish suitable products and goods.

121. As a result, an implied warranty of fitness for a particular purpose existed as to BEXTRA and CELEBREX.

122. BEXTRA and CELEBREX were not fit for their particular purposes because: (1) they caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including heart attacks, strokes and other serious and harmful adverse health effects, and (2) were not effective in decreasing gastrointestinal side effects.

123. BEXTRA and CELEBREX were not fit for their particular purpose as impliedly warranted causing the PFIZER ENTITIES to breach its implied warranty.

124. Plaintiffs, as consumers of BEXTRA and CELEBREX, were reasonably expected to use, consume and/or be affected by BEXTRA and CELEBREX.

125. The PFIZER ENTITIES' breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

126. WHEREFORE, Plaintiffs individually demand and pray for judgment against the PFIZER ENTITIES in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

D. Count IV: Breach of Express Warranty.

127. Plaintiffs adopt by reference Paragraphs 1 through 126.

128. The PFIZER ENTITIES expressly represented to Plaintiffs and other consumers and the medical community that BEXTRA and CELEBREX were safe and fit for their intended purpose, that they were of merchantable quality, that they did not produce any dangerous cardiovascular or other side effects, particularly any unwarned-of side effects and that they were adequately tested.

1. These warranties came in the form of:

a. The PFIZER ENTITIES' public written and verbal assurances of the safety and efficacy of BEXTRA and CELEBREX;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for BEXTRA and CELEBREX, which failed to warn of the risks of injuries inherent to the ingestion of BEXTRA and

CELEBREX, especially to the long-term ingestion of BEXTRA and CELEBREX;

c. Verbal and written assurances made by the PFIZER ENTITIES regarding BEXTRA and CELEBREX and downplaying the risks of injuries associated with the drugs;

d. False and misleading written information, supplied by the PFIZER ENTITIES, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing BEXTRA and CELEBREX during the period of Plaintiffs' ingestion of BEXTRA and CELEBREX, and;

e. advertisements.

2. The documents referred to above were created by and at the direction of the PFIZER ENTITIES.

3. The PFIZER ENTITIES knew or had reason to know that BEXTRA and CELEBREX did not conform to these express representations in that BEXTRA and CELEBREX are neither as safe nor as effective as represented and that BEXTRA and CELEBREX produce serious adverse side effects.

4. BEXTRA and CELEBREX did not and do not conform to the PFIZER ENTITIES' express representations because they are not safe, have numerous and serious side effects, including unwarned-of side effects and cause severe and permanent injuries.

5. Plaintiffs, other consumers and the medical community relied upon the PFIZER ENTITIES' express warranties.

6. The PFIZER ENTITIES' breach of express warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

129. WHEREFORE, Plaintiffs individually demand and pray for judgment against the PFIZER ENTITIES in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

E. Count V: Negligence.

130. Plaintiffs adopt by reference Paragraphs 1 through 129.

131. PFIZER and its predecessors were negligent in preparing, designing, researching, developing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling and/or distributing BEXTRA and CELEBREX. The PFIZER ENTITIES' negligence included, but is not limited to, the following:

a. The PFIZER ENTITIES negligently failed to provide any or adequate and proper warnings as to the dangers of the use of BEXTRA and CELEBREX for persons who were reasonably and foreseeably expected to use BEXTRA and CELEBREX, such as Plaintiffs named herein;

b. The PFIZER ENTITIES negligently failed to warn and failed to provide adequate instructions for the use of BEXTRA and CELEBREX for persons who were reasonably and foreseeably expected to use BEXTRA and CELEBREX, such as Plaintiffs herein;

c. The PFIZER ENTITIES negligently failed to investigate, perform adequate research and/or test for the hazards of BEXTRA and CELEBREX;

d. To the extent that THE PFIZER ENTITIES may have inquired as to the hazards of BEXTRA and CELEBREX, the PFIZER ENTITIES negligently failed to convey whatever knowledge or dangers, health hazards or safety precautions it may have had to the prescribers, users and consumers of BEXTRA and CELEBREX;

e. The PFIZER ENTITIES negligently failed to include adequate warnings with the drugs that would alert the medical, pharmaceutical and/or scientific communities and users and/or consumers of the drugs, including Plaintiffs, to the potential risks and serious side effects of the drugs;

f. The PFIZER ENTITIES negligently failed to adequately and properly test and inspect the drugs before placing the drugs on the market;

g. The PFIZER ENTITIES negligently failed to conduct sufficient testing and inspection of the drugs which, if properly performed, would have shown that the drugs had serious side effects, including but not limited to, an increased risk of adverse cardiovascular events and/or death;

h. The PFIZER ENTITIES negligently failed to adequately warn the medical, pharmaceutical and/or scientific communities, and users

and/or consumers of the drugs, including Plaintiffs, of the potential risks and other serious side effects associated with the drugs, including but not limited to an increased risk of serious thromboembolic and cardiovascular events and/or death;

i. The PFIZER ENTITIES negligently failed to conduct adequate pre-clinical testing and research to determine the safety of BEXTRA and CELEBREX;

j. The PFIZER ENTITIES failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of BEXTRA and CELEBREX;

k. The PFIZER ENTITIES negligently failed to provide adequate post-marketing warnings or instructions after the PFIZER ENTITIES knew, or should have known, of the significant risks associated with the use of BEXTRA and CELEBREX;

l. The PFIZER ENTITIES negligently failed to recall and/or remove BEXTRA and CELEBREX from the stream of commerce despite the fact that the PFIZER ENTITIES knew, or should have known, of the defective and unreasonably dangerous nature of the drugs, including the significant health risks associated with the use of the drugs; and

m. The PFIZER ENTITIES negligently encouraged the misuse and overuse of BEXTRA and CELEBREX while failing to disclose the side effects of the drugs to the medical, pharmaceutical and/or scientific

communities and users and/or consumers, including Plaintiffs, in order to make a profit from sales.

132. The PFIZER ENTITIES' negligence and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

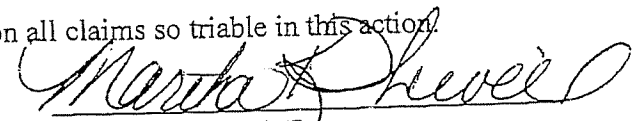
133. WHEREFORE, Plaintiffs individually demand and pray for judgment against the PFIZER ENTITIES in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

VII. DEMAND FOR JUDGMENT AGAINST DEFENDANTS PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).

WHEREFORE, Plaintiffs, Deanna K. Renyer and David W. Bloir, individually demand judgment of and from the PFIZER ENTITIES in an amount in excess of $75,000.00 and seek compensatory damages together with interest, cost of suit and attorney fees and for such other and further relief as the Court deems just and equitable.

VIII. DEMAND FOR JURY TRIAL.

Plaintiffs demand a trial by jury on all claims so triable in this action.



Martha K. Wivell, Esq.
MN Bar #0128090
Attorney at Law
Box 339
Cook, MN 55723
Telephone: (218) 666-0250
MWivell@MSN.com

Attorney for Plaintiffs and Local Counsel

– and –

Mark B. Hutton
Lead Counsel
KS Bar #10112
Trial.Lawyers@huttonlaw.com
Elizabeth L. Dudley
KS Bar #21582
Liz.Dudley@huttonlaw.com
HUTTON & HUTTON LAW FIRM, L.L.C.
8100 East 22nd Street North, Bldg. 1200
P.O. Box 638
Wichita, Kansas 67201-0638
Telephone: (316) 688-1166
Facsimile: (316) 686-1077
www.huttonlaw.com

Attorneys for Plaintiffs

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
DEANNA K. RENYER and
DAVID W. BLOIR

(b) County of Residence of First Listed Plaintiff Kansas
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
Pfizer, Inc., a Delaware Corporation; Pharmacia Corporation, a Delaware Corporation; and G.D. Searle LLC, a Delaware Corporation

County of Residence of First Listed Defendant AGENT FOR SERVICE OF PROCESS IN MPLS., MN
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Martha K. Wivell, Esq., #0128090
Suite 1025 Fifth Street, 100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 767-7500

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ Act	☐ 310 Airplane	☐ 362 Personal Injury—Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ Negotiable Instrument	☐ 315 Airplane Product Liability	☒ 365 Personal Injury—Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ Recovery of Overpayment & Enforcement of	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce/ICC Rates/etc.
☐ Medicare Act	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ Recovery of Defaulted Student Loans	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
(Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	SOCIAL SECURITY	☐ 490 Cable/Sat TV
☐ Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	☐ 861 HIA (1395ff)	☐ 810 Selective Service
☐ Other Contract	☐ 360 Other Personal		☐ 710 Fair Labor Standards Act	☐ 862 Black Lung (923)	☐ 850 Securities/Commodities Exchange
☐ Contract Product Liability			☐ 720 Labor/Mgmt Relations	☐ 863 DIWC/DIWW (405(g))	☐ 875 Customer Challenge 12 USC 3410
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 730 Labor/Mgmt Reporting & Disclosure Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
☐ Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 740 Railway Labor Act	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 790 Other Labor Litigation	FEDERAL TAX SUITS	☐ 892 Economic Stabilization Act
☐ Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General	☐ 791 Empl. Ret. Inc. Security Act	☐ 870 Taxes (U.S. Plaintiff	☐ 893 Environmental Matters
☐ Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 894 Energy Allocation Act
☐ Tort Product Liability	☐ 445 Amer. w/ Disabilities Employment	☐ 540 Mandamus & Other			☐ 895 Freedom of Information Act
☐ All Other Real Property	☐ 446 Amer. w/ Disabilities – Other	☐ 550 Civil Rights			☐ 900 Appeal of Fee Determination Under Equal Access to Justice
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			☐ 950 Constitutionality of State Statutes

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. Section 1332
Brief description of cause: Products Liability

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $ In excess of $75,000
CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): MDL 1699 Northern District of California
JUDGE DOCKET NUMBER MDL 1699

DATE 5/16/08 SIGNATURE OF ATTORNEY OF RECORD Martha K. Wivell

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE